
PROCEDURES

OFFICE OF COUNTER-TERRORISM AND EMERGENCY COORDINATION

**Procedures for the Office of Counter-Terrorism and Emergency Coordination
Counter-Terrorism Seminar (CT Seminar)**

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PURPOSE

This MAPP establishes procedures for preparing and conducting the monthly Office of Counter-Terrorism and Emergency Coordination (OCTEC) Counter-Terrorism (CT) Seminar (CT Seminar) by a CT Seminar coordinator.

BACKGROUND

In light of the terrorism attacks of September 11, 2001 (9/11), and the subsequent anthrax attacks, this monthly CT Seminar was first organized in 2003 to broaden the knowledge base for OCTEC personnel and medical countermeasure (MCM) review division personnel in the Office of New Drugs. The CT Seminar focuses on topics that align with one of the elements of OCTEC's mission, i.e., to facilitate the development and availability of safe and effective medical countermeasures (MCMs) for chemical, biological, radiological, and nuclear threats. Topics range from presentations associated with counterterrorism-related science to the research and development of MCMs against threat agents. Personnel from CDER, other FDA Centers or Offices, and external agencies such as NIH are commonly invited depending on the topic of the seminar.

RESPONSIBILITIES

CT Seminar Speaker Selection Officer

- An OCTEC Medical Officer selects potential speakers based on topics that may benefit OCTEC personnel.
- Obtains concurrence on the selected speaker from the OCTEC Office Director.

CT Seminar Coordinator

- Adheres to the procedures below to prepare and conduct the monthly CT Seminar.
- Collaborates with the CT Seminar Speaker Selection Officer.
- Communicates with the selected speaker to provide the CT Seminar logistics and obtains information, such as the biography and slides, to include in the meeting invitation.

PROCEDURES

CT Seminar Speaker Selection Officer

1. Selects a subject and a list of potential speakers.
2. Discusses the potential speakers with the OCTEC Office Director for concurrence.
3. Invites the speaker.
4. Informs the speaker that the OCTEC CT Seminar Coordinator will be in contact with logistical details.
5. When a speaker has been confirmed, promptly informs the CT Seminar Coordinator, ideally at least four (4) weeks prior to the CT Seminar date.
6. If a speaker or any attendee is a Foreign Visitor, informs the CT Seminar Coordinator at least five (5) weeks prior to the CT Seminar thus providing the additional time needed to complete a Foreign Visitor Data Request form.

CT Seminar Coordinator

1. Sends a Foreign Visitor Data Request (FVDR) form (Attachment 1) to the speaker five (5) weeks prior to the CT Seminar if a speaker or any attendee is a Foreign Visitor. Note: HHS policy requires that all visits involving foreign visitors be approved in advance by an FDA or HHS security official. Refer to FDA's Standard Operating Procedure for Hosting Foreign Visitors which is available from the Office of International Programs/Office of Security Operations.
2. Reserves a recurring, monthly CT Seminar meeting for all OCTEC personnel as a placeholder on their calendars (e.g., on third Tuesday each month between 1-2 PM).
3. Uses the Outlook Global Address Book or the Event Management System (EMS, link at <http://fdswv03842/virtualEMS/>), to select a conference room capable of seating approximately 30 individuals, e.g., the typical number of seminar attendees. Reserves the room for an extra 30 minutes prior to the CT Seminar starting time to prepare for the seminar and an extra 30 minutes for going beyond the hour for the seminar with extended question and answers (Q&As).
4. At least three weeks prior to the CT Seminar:
 - a. Obtains the following information from the speaker:
 - Title of the CT Seminar presentation.

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- Summary of the presentation (1-2 paragraphs).
 - Speaker's biography (1-2 paragraphs) including credentials, title, and affiliation.
 - Completed FVDR form. Note: Ensure this form is sent to OSO-FOREIGN VISIT (Global Address Book) at least 10 business days prior to the CT Seminar. If the FVDR form is not received in a timely manner, the speaker or attendee may be denied access.
- b. Ensures OCTEC administrative staff arranges travel for out-of-town speakers and their guest(s).
5. Updates the meeting invitation as information becomes available. Depending on the topic of the seminar, extends an invitation to personnel from the Office of New Drugs' review divisions, other FDA Centers, or other agencies (e.g., NIH).
6. Reserves the OCTEC conference line from the Outlook Global Address Book as "CDER OCTEC CONF LINE" when all attendees are from within the agency. If attendees are from external agencies, reserves a conference call via 1-877-855-4797 and includes the number and passcode in the Outlook invitation.
7. Reserves the OCTEC car via the Outlook Global Address Book as "CDER OCTEC CAR" because OCTEC attendees will travel to the White Oak (WO) campus for the seminar. If needed, an extra car can be reserved via OCTEC administrative staff.
8. Contacts the speaker and provides the seminar date, time, and location. Also provides the WO campus address, directions, and campus map, if needed. Refer to the FDA White Oak Driving Directions and Parking information link below for this information:
<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241748.htm>.
9. At least one week prior to the CT Seminar:
- a. Enters each non-FDA speaker and non-FDA attendee name and their email addresses into the LobbyGuard system and generates an email to them containing a barcode to be used at the security desk for building access on the day of the seminar. For LobbyGuard questions or training, email "FDA-Visitor Management" at FDA-VisitorManagement@fda.hhs.gov.
 - b. Verifies that the non-FDA speaker/non-FDA attendee receives an email containing a LobbyGuard barcode. Advises the speaker/attendee that to gain entrance to the building, a hardcopy of the email and valid photo identification should be brought to the designated building lobby at the FDA WO campus. Assures speaker/attendee that if they do not have their email, an OCTEC staff member will meet them in the building lobby with a hardcopy of the barcode; however, valid photo identification will be necessary.
 - c. If LobbyGuard is not functional, emails a visitor list to WO Campus Security (FDA-Physical Security) at FDA-PhysicalSecurity@fda.hhs.gov.
 - d. Obtains the speaker's slides and permission to share them with the attendees. If permission is granted, post them on the FDA intranet. If the speaker denies permission, establish an Adobe Connect Pro meeting using the following information:
 - Browse Adobe Connect Pro "Getting Started Guide" at <http://collaboration.fda.gov/common/help/en/support/startmain.htm>

- Contact ERIC by email (FDA ERIC) or by phone 301-827-3742.
 - Email questions to AdobeConnectProAdmin@fda.hhs.gov
 - e. For a late notice speaker or attendee and other questions, contact the FDA Office of Security Operations at (301) 796-4606.
10. On the day before the CT Seminar:
- a. Prepares Seminar Attendee Roster (Attachment 2).
 - b. Makes double-sided presentation handouts for meeting attendees.
 - c. Prints a copy of the LobbyGuard barcode to bring to the seminar in case the speaker or any attendee does not bring a copy.
 - d. Ensures that all seminar equipment (e.g., microphone, laptop, projector, screen, and boomerang phone) in the meeting room is in good working condition.
11. On the day of the CT Seminar:
- a. Sends a reminder email to all attendees early in the morning.
 - b. If the speaker's slides were obtained before the seminar, uploads the presentation to the laptop computer in the meeting room at least 15 minutes prior to the meeting.
 - c. Prior to the seminar starting time, meets the speaker and any external attendees at the lobby of the designated FDA WO building. Assists participants to scan the barcode contained in the hardcopy of their email under the barcode scanner of the LobbyGuard machine and follow the steps of the program to complete the security process. LobbyGuard will generate a temporary access pass for the speaker and any external attendees. Note: Foreign visitors will be individually verified by a FDA Security representative who will review their passport or other national identity source document (i.e., the document which allowed the immigration into the United States).
 - d. Escorts the speaker and attendees to the meeting room from the Lobby. If needed, obtains assistance from other OCTEC personnel to escort the speaker and attendees to the meeting room.
 - e. Assists the speaker with the presentation equipment to assure familiarity.
 - f. Opens and facilitates the seminar.
 - g. Thanks the speaker and attendees.
 - h. Escorts the speaker and any external attendees to the lobby exit.
12. After the CT Seminar, updates the speaker list and files the slides on the OCTEC intranet.

REFERENCES

- OCTEC Mission: <http://inside.fda.gov:9003/CDER/OfficeofCounter-TerrorismandEmergencyCoordination/ImmediateOffice/default.htm>
- White Oak Campus Information-Campus Security including LobbyGuard: <http://inside.fda.gov:9003/AboutFDA/BuildingResources/WhiteOakCampusInformation/cm033776.htm>
- Event Management Systems (EMS) Room Request: <http://fdswv03842/virtualEMS/RoomRequest.aspx?data=ity3Dem%2byxxGFZTQvNr97%2f1xAeUr7Uub>

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- Foreign Visitor Data Request Form, in the Meeting Request Granted Letter (PIND/IND/NDA/BLA) Template:
http://eroom.fda.gov/eRoom/CDER2/CDERStandardLettersCommittee/0_14075
 - FDA's Standard Operating Procedure for Hosting Foreign Visitors, available from the Office of International Programs/Office of Security Operations (OSO-FOREIGN VISIT in the Global Address Book).
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DEFINITIONS

Adobe Connect Pro - is a Web conferencing and training solution for real-time meetings, eLearning, and online presentations that audiences can see and hear anytime, anywhere, through any standard web browser.

CT Seminar coordinator - is the OCTEC employee who regularly prepares and facilitates CT seminars.

CT Seminar Speaker Selection Officer - is an OCTEC Medical Officer who selects potential speakers based on topics that may benefit OCTEC personnel.

Foreign national - An individual who is not a U.S. citizen is considered to be a foreign national. If an individual has dual citizenship (U.S. and another country) or permanent resident status, the individual is not considered to be a foreign national.

Foreign visitor - Any foreign national who does not have a valid U.S. Federal Government Agency issued Security Identification Access Badge/Card is considered to be a foreign visitor.

Escort - An individual who personally accompanies, and closely monitors, a foreign visitor during their visit to an FDA/HHS facility. Multiple escorts may accompany and monitor a foreign visitor during their visit to an FDA/HHS facility. For example, one escort may greet the foreign visitor at the reception facility and accompany the visitor to the first meeting area. Another escort may accompany the foreign visitor to the next meeting area. All escorts must have a valid FDA Security Identification Badge/Card. Escorts may be foreign nationals provided that they have been issued an FDA Security Identification Access Badge/Card. Students/interns are not authorized to act as escorts for foreign visitors.

Escorting foreign visitors - On the day of the visit, foreign visitors will be individually verified by a FDA Security representative who will review their passport or other national identity source document (i.e., the document which allowed the immigration into the United States).

LobbyGuard - A new visitor management system that will allow FDA employees a more manageable way of scheduling domestic and foreign visitors onto the FDA White Oak Campus. LobbyGuard is a touch screen kiosk that registers visitors, takes their pictures, and prints temporary passes for the visitors to the FDA at the White Oak Campus.

Permanent resident - A noncitizen who has been lawfully granted the privilege of residing and working permanently in the United States. Individuals with permanent resident status are not considered to be foreign nationals.

Valid photo identification - Includes state driver's licenses for U.S. citizens and passports for all foreign nationals. Permanent residents are exempt from submitting the FVDR form, but must produce their permanent resident card prior to entering the facility. A state driver's license on its own is not sufficient proof of permanent residence.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions

ATTACHMENT 1: Foreign Visitor Data Request Form

VISITORS FULL NAME (First, Middle, Last)	
GENDER	
COUNTRY OF ORIGIN/CITIZENSHIP	
DATE OF BIRTH (MM/DD/YYYY)	
PLACE OF BIRTH (city and country)	
PASSPORT NUMBER COUNTRY THAT ISSUED PASSPORT ISSUANCE DATE: EXPIRATION DATE:	
VISITOR ORGANIZATION/EMPLOYER	
MEETING START DATE AND TIME	
MEETING ENDING DATE AND TIME	
PURPOSE OF MEETING	
BUILDING(S) & ROOM NUMBER(S) TO BE VISITED	
WILL CRITICAL INFRASTRUCTURE AND/OR FDA LABORATORIES BE VISITED?	
HOSTING OFFICIAL (name, title, office/bldg, room number, and phone number)	

ESCORT INFORMATION (If different from Hosting Official)	
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Date:[illegible]